UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: 4/16/18

Subject: Efficacy Review for PERACLEAN 5, EPA Reg. No. 54289-3
(DP Barcode: 445252, E-Submission: 25381)

From: Samantha Collins
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Thru: Kristen Willis, Efficacy Team Leader
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To: Zeno Bain / Terria Northern
Regulatory Management Branch
Antimicrobials Division (7510P)

Applicant: EVONIK CORPORATION

Formulation from the Label:

Active Ingredient(s)	% by wt.
Hydrogen Peroxide	26.5%
Peroxyacetic Acid	4.9%
Other Ingredients	68.6%
Total	100.0%

I BACKGROUND

Product Description (as packaged, as applied): Liquid concentrate

Submission type: Label amendment

Currently registered efficacy claim(s): Hard, non-porous, concentrate sanitizer (food and non-food contact), and hard surface disinfectant product when diluted in 400 ppm hard water at a 10- minute disinfection contact time and 1-minute sanitization contact time.

Requested action(s): Add organism (*Listeria monocytogenes* (ATCC 19117) to food contact sanitization claims.

Documents considered in this review:

- Letter from applicant to EPA dated December 18, 2017
- Data Matrix (EPA Form 8570-35)
- 1 efficacy studies (MRID 50471101)
- Proposed label dated 12/15/2017
- Confidential Statement of Formula (EPA Form 8670-4) dated 2/25/1989.

II PROPOSED DIRECTIONS FOR USE

pre-treatment prior to sanitization of food-contact surfaces
Peraclean 5 can be used as a pre-treatment on food contact prior to sanitization. For use dilute 3.5 -17.5 fl. oz of PERACLEAN® 5 in 5 gallons of water, this will provide 300-1500 ppm peroxyacetic acid. Let soak for 15 minutes and follow with a potable water rinse.

Sanitization
NOTE: FOR MECHANICAL OPERATIONS prepared use solution may not be used for subsequent sanitizing but may be reused for other purposes such as cleaning. FOR MANUAL OPERATIONS fresh sanitizing solutions should be prepared at least daily or more often if the solution becomes diluted or soiled.
PERACLEAN® 5 peroxyacetic acid sanitizer is recommended for use on precleaned surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in dairies, breweries, wineries, beverage and food processing/packing plants, egg processing/packing equipment surfaces, and eating establishments. This product is effective as a sanitizer when solution is prepared in water of up to 400 ppm hardness as CaCO3. This product has demonstrated greater than a 99.999% reduction of survivors after a 60 second exposure period in the AOAC Germicidal and Detergent Sanitizing Action of Disinfectants study.
Sanitizing Food Contact Surfaces

Effective against *Staphylococcus aureus* [(ATCC 6538)] and *Escherichia coli* [(ATCC11229)], *Pseudomonas Aeruginosa* [(ATCC 15442)] *Salmonella typhimurium* [(ATCC 23564)] and *Listeria Monocytogenes* [(ATCC 191170].
Prior to sanitizing, remove gross food particles, then wash with a detergent solution, followed by a potable water rinse. Sanitize with a concentration of 1.0 to 1.5 fl. oz. PERACLEAN® 5 dissolved in 5 gallons of water (0.16 to 0.22% v/v concentration). This will provide 88 to 130 ppm of peroxyacetic acid. At this dilution PERACLEAN® 5 is effective against Staphylococcus aureus and Escherichia coli and Salmonella typhimurium [(ATCC 23564)]. For use against Pseudomonas aeruginosa prepare a sanitizing solution by adding 2.1 to 2.3 fl. oz. PERACLEAN® 5 dissolved in 5 gallons of water. This will provide 180-200 ppm of peroxyacetic acid. For use against *Listeria monocytogenes* prepare a sanitizing solution by adding 2.3 fl. oz. PERACLEAN® 5 dissolved in 5 gallons of water. This will provide 200 ppm of peroxyacetic acid. Use immersion, coarse spray or circulation techniques as appropriate to the equipment. All surfaces should be exposed to the sanitizing solution for a period of at least 60 seconds or more if specified by governing sanitary code. Allow sanitized surfaces to adequately drain before contact with food so that little or no residue remains. Do not rinse.

III STUDY SUMMARIES

1.	**MRID**	50471101	**Study Completion Date:**	11/15/2017			
Study Objective		Food Contact Sanitizer					
Testing Lab; Lab Study ID		*Accuratus Lab Services, A24126*					
Test organism(s) **☒ 1 ☐ 2 ☐ 3 ☐ 4+**		*Listeria monocytogenes* (ATCC 19117)					
Test Method		Germicidal and Detergent Sanitizing Action of Disinfectants					
Application Method		Liquid					
Test Substance Preparation	**Name/ID**	Peraclean 5					
	Lots **☐ 1 ☒ 2 ☐ 3**	8257051301 and 8257051302					
	Preparation	Tested concentration: Nominal[WK1] Dilution: 0.47 fl oz/1 gallon (200 ppm) Diluent: 400 ppm AOAC Synthetic Hard Water					
Soil load		None					
Carrier type, # per lot		Liquid Suspension, 1 per batch					
Test conditions		**Contact time**	30 second	**Temp**	25°C	**RH**	N/A
Neutralizer		Letheen Broth + 0.1% Sodium Thiosulfate + 0.01% Catalase					
Reviewer comments (i.e. protocol deviations and amendments, retesting, etc.)							

IV STUDY RESULTS

Food Contact Surface Sanitization Efficacy (MRID 50489101)

Batch	Organism	Cfu/mL	Log Reduction	Average log_{10} CFU/Carrier
30-second contact time, 400 ppm water, no soil load, 0.47 fl oz/1 gallon (200 ppm)				
8257051301	*Listeria monocytogenes* (ATCC 19117)	<1 CFU/mL (<0.00 Log_{10})	>7.70	5.0 x 10^7 CFU/mL (7.70 Log_{10})
8257051302		<1 CFU/mL (<0.00 Log_{10})	>7.70	

V STUDY CONCLUSIONS

MRID	Claim	Surface Type	Application Method(s) and Dilution	Contact Time	Soil load	Diluent	Organism(s)	Data support tested conditions?
50471101	Food Contact Sanitizer	Hard, non-porous surfaces	0.47 fl oz/1 gallon 400 ppm AOAC Synthetic Hard Water	30 second	N/A	400 ppm AOAC Synthetic Hard Water	• *Listeria monocytogenes* (ATCC 19117)	**Yes**

VI LABEL COMMENTS

Label Date: 12/15/2017

1. The proposed label claims that the product, PERACLEAN 5, EPA Reg. No. 54289-3, when diluted at 0.47 fl oz/1 gallon 400 ppm AOAC Synthetic Hard Water, is an effective food contact sanitizer against the following on hard, non-porous surfaces in no organic soil for a 1-minute contact time:

   Listeria monocytogenes (ATCC 19117)

   These claims are **acceptable** as they are supported by the submitted data.

2. Make the following changes to the proposed label:

   a. On the proposed label, correct the ATCC number for *L. monocytogenes*, change *Listeria monocytogenes* (ATCC 191170) to *Listeria monocytogenes* (ATCC 19117).
   b. Under the heading "Sanization of Conveyers and Equipment for Meat, Poultry, Seafood, Fruit, Nuts and Vegetables" revise the directions for use to indicate that surfaces should be pre-cleaned prior to sanitization. The product was not tested as a food contact sanitizer with soil.
   c. Under the "Combination Disinfection and Cleaning" heading, revise the statement "When used as directed, PERACLEAN 5 is specifically designed to disinfect, deodorize and clean inanimate, hard, surfaces…." To "When used according to the directions for disinfection, PERACLEAN 5 is specifically designed to disinfect, deodorize and clean inanimate, hard, non-porous surfaces…."
   d. Under the "For treatment of Raw, Unprocessed Fruit and Vegetable Surfaces" remove the directions for use for fogging. Adjunct fogging claims are not permitted: https://www.epa.gov/pesticide-registration/fogger-and-mister-final-signed-lette.
   e. Under the "Fruit and Vegetable Water Treatment" heading, revise the direction to "Apply the diluted sanitizer solution." References to sanitizer are not permitted for non-public health claims.
   f. Under the "Surfaces Treated to Control the Spread of Citrus Canker" heading remove all mentions of sanitizing and sanitizer. References to sanitizer are not permitted for non-public health claims.

Note to PM: Please verify that the registrant has data on file to support the citrus canker use.